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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,562	10/24/2000	Dr. Max Schaldach	7040-5	1946

21324            7590            12/18/2002  
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[REDACTED] EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
	3738

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/695,562	SCHALDACH ET AL. <i>Cr</i>	
	Examiner William H. Matthews (Howie)	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 December 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-4,7,10-12,14 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 2-4,7,10-12,14 and 17-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on 10 October 2002 is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## DETAILED ACTION

### *Drawings*

1. The corrected or substitute drawings were received on October 7, 2002. These drawings are acceptable.

### *Specification*

2. The substitute specification has been reviewed and accepted. Furthermore amendments to the specification received on October 7, 2002 have been entered. Applicant is no longer required to furnish a statement of no new matter or a marked up copy of the substitute specification because the Examiner has determined the substitute specification to be acceptable.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 2-4,7,10-12,14,17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 18, and dependent claims 2-4,7,10-12,14,19-25 are indefinite because of the limitations "an irregular coating" in line 1 of each independent claim.

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Irregular may be interpreted as "abnormal/ unusual" or "lacking symmetry/unevenness" as defined in Merriam-Webster's Collegiate Dictionary 10<sup>th</sup> Edition.

Furthermore, the limitation "the spacings of the coating islands" in line 1 of claim 10 is indefinite because it lacks proper antecedent basis.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 2-4,7,10,11,14,17,18,20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Yan US PN 5,843,172.

Regarding claim 17, figure 12 shows a stent having coating islands spaced farther apart where a greater degree of local stretching or expansion occurs. During radial expansion, the innermost layer coating islands (bottom, 112) will experience greater stress concentrations than the outermost layer coating islands (top, 110). More specifically, if the bottom layer (112) faces the vessel lumen and the upper layer (110) faces the vessel wall, the spacing between the coating islands adjacent to base (108) have greater spacing than the spacing between the outer coating islands (114).

Regarding claim 18, figure 12 also shows smaller coating islands (114) where greater degrees of local stretching occur (bottom, 112) as compared to coating islands adjacent to base (108).

Regarding claims 2-4, 11, and 20-23, a biocompatible and irregularly (or non-uniformly) formed patterned-configuration surface coating having locations where the coating is missing completely is shown in figure 12. Note that base (108) is coated with multiple layers of coating islands progressively decreasing in size above and below the base (108). Furthermore, note that a random pattern fulfills a patterned configuration.

Regarding claims 7 and 14, substantially round coating islands of equal size are shown in figure 12.

Regarding claim 10, figure 12 clearly shows a given region having equally spaced coating islands.

#### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 12,19,24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan US PN 5,843,172 in view of Amon et al. US PN 5,849,206.

Yan discloses a stent meeting the structural limitations of claims 12,19,24, and 25 as described in the 102(e) rejection above, but lacks the express written disclosure

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of the coating islands comprising hydrogenated amorphous silicon carbide (a-SiC:H).

Amon et al. teaches a stent having a biocompatible coating comprising a-SiC:H in order to provide strong adherence between the stent and coating during expansion to prevent flaking and to provide exceptional blood compatibility. See line 21 of column 1 through line 54 of column 2, lines 58-65 of column 3, and figure 1.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the stent coating islands disclosed by Yan by including a-SiC:H as taught by Amon et al. in order to provide strong adherence between the stent and coating during expansion to prevent flaking and to provide exceptional blood compatibility.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WJM

WHM

December 14, 2002

*Corrine McDermott*  
CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700